



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

Our STN: BL 103694/1009 (replaces Ref. No. 99-1472)

SEP 18 2002

Genetics Institute, Incorporated  
c/o Tracy D. Rockney  
Wyeth Pharmaceuticals  
150 North Radnor-Chester Road  
St. Davids, PA 19087

Dear Ms. Rockney:

Your request to supplement your biologics license application for Oprelvekin to revise the physician package insert to update the Warnings and Precautions sections and to add important new safety information has been approved.

We acknowledge your written commitment as described in your facsimile (to be followed in official hard copy) of September 17, 2002, to submit a revised patient package insert to STN 103694/5014 by September 27, 2002.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Karen D. Weiss, M.D.

Director

Division of Clinical Trial Design  
and Analysis

Office of Therapeutics  
Research and Review

Center for Biologics  
Evaluation and Research

Enclosure